

**REMARKS**

Applicants appreciate the Examiner's thorough examination of the subject application. Applicants respectfully request reconsideration of the subject application based on the following remarks.

Claims 1-19 are currently pending in the application. Claims 4-19 have been withdrawn from consideration without prejudice. Accordingly, Claims 1-3 are under current examination.

**I. Rejections Under 35 U.S.C. § 102(e)**

Claims 1-3 are rejected under 35 U.S.C. § 102(e) as being anticipated by Feger et al. (U.S. Patent No. 6,465,428 B1). The Examiner states that Feger et al. teaches the claimed invention.

Without admission that Feger et al. teaches or suggests the invention as currently claimed in claims 1-3, it is respectfully submitted that the subject matter disclosed in U.S. Patent No. 6,465,428 B1 and the claimed invention as claimed in claims 1-3 were, at the time the invention was made, subject to an obligation of assignment to the same person. In support thereof, executed assignments to the same entity for the above-identified application for U.S. patent and the subject matter disclosed in U.S. Patent No. 6,465,428 B1 are submitted herewith. Given that the subject matter disclosed in U.S. Patent No. 6,465,428 B1 and the claimed invention were, at the time the invention was made, subject to an obligation of assignment to the same person, rejections based upon U.S. Patent No. 6,465,428 B1 are inappropriate and should be discontinued.

**II. Rejections Under 35 U.S.C. § 103(a)**

A. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Bounine et al., Conrath et al., or WO 98/22107 (abstract) taken with Urawa et al. or Maiti et al.

The Examiner states that Bounine et al., Conrath et al., and WO 98/22107 all teach that the combination of quinopristine/dalfopristine is known in the art to be used as an antibiotic. The Examiner also states that Urawa et al. and Maiti et al. teach that cefpirome is known in the art to be used as an antibiotic. The Examiner further states that since the individual components are known to be used individually in the art for the same purpose, then to use them together in one composition is obvious.

Applicants respectfully disagree.

Claim 1 is directed to:

A pharmaceutical composition comprising synergistically effective amounts of (A) cefpirome and (B) a dalfopristine/quinupristine combination.

Applicants note that the use of such synergistic combinations of quinupristine/dalfopristine with cefpirome has been found to provide a particular advantage in the treatment of infections over the use of either composition alone (see Specification, paragraph [013]). Specifically, the synergistic action of the combination according to Claim 1 provides a much higher potency than the action of either quinupristine/dalfopristine or cefpirome when used alone. Moreover, when the two are used in combination it has been surprisingly discovered that it is now possible to decrease quinupristine/dalfopristine or cefpirome concentration within a dose, or to increase the time between administration of the doses required to inhibit or eradicate a chosen bacterium (see Specification, paragraph [018]).

Furthermore, the synergistic activity of the combination, as claimed, makes it possible to treat infections for which each of the compositions, administered in monotherapy, would not be effective. By way of example, neither quinupristine/dalfopristine nor cefpirome show any effectiveness *in vivo* in monotherapy in rats infected with, for example, a strain of C-MLS<sub>B</sub>-resistant MRSA (see Specification, paragraph [020]). However, it is shown that the unique quinupristine/dalfopristine combination with cefpirome is effective in more than 90% of rats infected with a strain of C-MLS<sub>B</sub>-resistant MRSA (see Specification, paragraph [020]). One of skill in the art

would neither predict nor expect these surprising results based on the fact that quinupristine/dalfopristine and ceftiofime are each known in the art to be used in monotherapy antibiotic treatment.

It is respectfully submitted that Bounine et al., Conrath et al., and WO 98/22107 do not teach or suggest to administer quinupristine/dalfopristine in combination with ceftiofime or that such results now discovered could be achieved if they were co-administered.

Urawa et al. and/or Maiti et al. do not cure the deficiencies of Bounine et al., Conrath et al., and WO 98/22107. Neither Urawa et al. nor Maiti et al. teach or suggest that either dalfopristine/quinupristine or ceftiofime may have increased efficacy when administered together, as now claimed.

It is therefore respectfully submitted that this rejection is overcome and should be discontinued.

B. Claims 1-3 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Feger et al.

Applicants respectfully disagree. For the same reasons discussed above in response to the Examiner's rejection under § 102(e), it is respectfully submitted that rejections based upon Feger et al. are improper and should be discontinued.

In view of the above, it is believed that Claims 1-3 are in immediate condition for allowance. Favorable reconsideration and early allowance of this application for U.S. patent, therefore, is earnestly solicited.

Applicants believe that additional fees are not required to complete the filing requirements for the subject application or otherwise in connection with this submission. However, if a fee is required, including any extension of time fees, a fee paid is inadequate or credit is owed for any excess fee paid, the Commissioner for Patents is hereby authorized and requested to charge/credit Deposit Account No. **04-1105**.

Dated: 6/22/04

Respectfully submitted,

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